CORPORATE COMPLIANCE AGREEMENT

BETWEEN THE

OFFICE OF INSPECTOR GENERAL

OF THE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

AND

LIFESCAN, INC.

I. PREAMBLE

LifeScan, Inc. ("LifeScan"), a corporation and wholly owned subsidiary of Johnson & Johnson Company, hereby enters into this Corporate Compliance Agreement ("CCA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to facilitate a Settlement Agreement with the United States pursuant to a *qui tam* claim brought under the False Claims Act (the "Settlement Agreement") based on violations of the Federal Food, Drug, and Cosmetic Act (the "Act"), to wit, causing to be introduced and delivering for introduction into interstate commerce medical devices which were misbranded, failing to furnish material information with respect to blood glucose monitors, and submitting false and/or misleading reports to the Food and Drug Administration ("FDA" or the "Agency"). LifeScan develops, designs, manufactures, distributes and sells medical devices called blood glucose monitoring systems, which includes a blood glucose meter and related products such as a lancet and chemically treated white melenix test strips.

LifeScan has separately agreed to undertake certain actions designed to promote LifeScan's compliance with FDA standards. LifeScan enters into this CCA to supplement those actions and to promote compliance with 42 U.S.C. § 1320a-7b(b) and applicable regulations thereunder (the "Program Requirements") by its officers, directors, and employees ("Covered Persons"). This CCA is incorporated by reference into the Settlement Agreement.

LifeScan has represented prior to the execution of this CCA that it voluntarily established a health care compliance program ("Compliance Program"), which provides for corporate compliance policies and procedures and which, as represented by LifeScan, is designed to promote conformity with the Program Requirements. Therefore, pursuant to this CCA, LifeScan hereby agrees to maintain in full operation its Compliance Program for the term of this CCA. The Compliance Program may be modified by LifeScan as appropriate, but at a minimum, shall always comply with the obligations enumerated in this CCA.

II. TERM OF THE CCA

The period of the compliance obligations assumed by LifeScan under this CCA shall be three (3) years from the effective date of this CCA (unless otherwise specified). The effective date of this CCA shall be the date on which the final signatory of this CCA executes this CCA.

Sections VII, VIII, IX, X and XI shall remain in effect until the OIG has completed its review of the final annual report, which review shall be completed within a reasonable period of time after the OIG's receipt of such report, but no later than 120 days therefrom.

III. CORPORATE COMPLIANCE OBLIGATIONS

LifeScan hereby agrees to maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* LifeScan has represented to the OIG that, pursuant to its Compliance Program, it has created a health care compliance officer position ("Compliance Officer"). LifeScan shall formally maintain the appointment of an individual to serve as LifeScan's Compliance Officer. At a minimum, the Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to promote compliance with the requirements set forth in this CCA. The Compliance Officer shall be a member of senior management of LifeScan, shall make periodic (at least quarterly) reports regarding compliance with this CCA directly to the Board of Directors of LifeScan, and shall be authorized to report on such matters to the Board of Directors of LifeScan at any time. At a minimum, the Compliance Officer shall be responsible for monitoring compliance with this CCA as well as for any reporting obligations created under this CCA.

Any changes in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CCA, must be reported to the OIG, in writing, within 15 days of such a change.

2. *Compliance Committee.* LifeScan shall maintain its existing Health Care Compliance Project Team ("Project Team"), which shall at a minimum, include the Compliance Officer, any other persons deemed necessary by LifeScan to meet the requirements of this CCA, and a member of the LifeScan Board of Directors. The Compliance Officer shall chair the Project Team and the Project Team shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

B. Written Standards.

1. *Code of Conduct.* Pursuant to its Compliance Program, LifeScan will create a Code of Conduct. The Code of Conduct shall be distributed to all Covered Persons within 90 days of the effective date of this CCA. LifeScan shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all Covered Persons. The Code of Conduct shall, at a minimum, set forth:

a. LifeScan's commitment to full compliance with applicable Program Requirements;

b. LifeScan's requirement that all of its Covered Persons shall be expected to comply with this CCA and with LifeScan's own Policies and Procedures as implemented pursuant to section III.B;

c. the requirement that all of LifeScan's Covered Persons shall be expected to report to the Compliance Officer or any other individual designated by LifeScan suspected violations of this CCA or any of LifeScan's own Policies and Procedures;

d. the possible consequences to both LifeScan and Covered Persons of failure to comply with this CCA and with LifeScan's own Policies and Procedures or of failure to report such non-compliance; and

e. the right of all individuals to use the Disclosure Program described in section III.E, and LifeScan's commitment to maintain confidentiality, as appropriate, and non-retaliation with respect to disclosures.

Within 90 days of the effective date of the CCA, each Covered Person shall certify, in writing or by electronic signature, that he or she has received, read, understood, and will abide by LifeScan's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within two weeks after becoming a Covered Person or within 90 days of the effective date of the CCA, whichever is later.

LifeScan shall annually review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any such revised Code of Conduct shall be distributed within 30 days of finalizing such changes. Covered Persons shall certify that they have received, read, understood and will abide by the revised Code of Conduct within 60 days of the distribution of such revisions.

2. *Policies and Procedures.* LifeScan has represented that it will implement certain policies and procedures designed to promote compliance with FDA standards. In addition, LifeScan has represented to the OIG that, pursuant to its Compliance Program, it has created written policies and procedures regarding LifeScan's Compliance Program, entitled "The LifeScan Regulatory Guidance Document Summaries," a copy of which has been submitted to the OIG. To the extent not already accomplished, within 120 days of the effective date of this CCA, LifeScan shall implement written Policies and Procedures regarding the operation of LifeScan's compliance program and its compliance with the Program Requirements. At a minimum, the Policies and Procedures shall address:

a. the subjects relating to the Code of Conduct identified in section III.B.1; and

b. the obligations of LifeScan under this CCA.

Within 120 days of the effective date of the CCA, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions are related to those Policies and Procedures. Appropriate and knowledgeable staff should be available to explain the Policies and Procedures.

At least annually (and more frequently if appropriate), LifeScan shall assess and update as necessary the Policies and Procedures. Within 30 days of the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all individuals whose job functions are related to those Policies and Procedures.

C. Training and Education.

1. *General Training.* LifeScan has represented to the OIG that, pursuant to its Compliance Program, it has conducted compliance training and education of its employees. LifeScan shall formally maintain the compliance training and education of its employees. Within 90 days of the effective date of this CCA, LifeScan shall provide at least one hour of general training to each Covered Person. This training, at a minimum, shall explain LifeScan's:

a. CCA requirements;

b. Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues); and

c. The existence of the Disclosure Program under section III.E.

New Covered Persons shall receive the general training described above within 30 days of becoming a Covered Person or within 90 days after the effective date of this CCA, whichever

is later. After receiving the initial training described above, each Covered Person shall receive the general training annually. LifeScan may satisfy its obligation to provide general training through the dissemination of written materials to Covered Persons provided that they are informed in such written materials that they have the opportunity to discuss any questions or issues related to the training with the Compliance Officer or his or her designee.

2. *Specific Training.* Within 180 days of the effective date of this CCA, each Covered Person whose job functions are directly related to the Policies and Procedures addressing the Program Requirements, as well as contractors whose job functions for LifeScan are directly related to the Policies and Procedures addressing the Program Requirements (hereinafter collectively referred to as "Relevant Covered Persons"), shall receive at least two hours of specific training in lieu of the general training required above. This specific training shall include a discussion of:

a. the consequences of selling adulterated and/or misbranded medical devices, including the possibility of legal action brought by the United States or a relator on behalf of the United States;

b. the application of the Program Requirements to the marketing and selling of medical devices and products; and

c. The obligation not to provide information to customers or encourage the submission of information by customers that would lead to the submission of false claims.

Persons providing the training must be knowledgeable about the subject area.

New Relevant Covered Persons shall receive this training within 60 days after becoming Relevant Covered Persons or within 180 days after the effective date of this CCA, whichever is later. A LifeScan employee who has completed the specific training shall review a new Relevant Covered Person's work relevant to this CCA until such time as the new Relevant Covered Person completes applicable training.

After receiving the initial training described in this section, every Relevant Covered Person shall receive specific training annually.

A copy of all training materials used for the training required by section III.C, a description of such training, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held shall be maintained by LifeScan and made available to the OIG upon request.

3. *Certification*. Each individual who is required to attend training shall certify, in writing or by electronic signature, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or his or her qualified designee) shall retain the certifications, along with all course materials. These shall be made available to the OIG, upon request.

4. *General Meeting*. LifeScan has represented that it will hold a general meeting with its employees concerning its agreements relating to compliance with FDA standards. At such meeting, LifeScan shall also describe the terms and conditions of this CCA to its employees.

D. Annual Independent Audit Requirement.

LifeScan certifies that it has independently agreed to provide reports to FDA, and to periodic independent compliance audits, with respect to certain FDA compliance matters pursuant to a matter captioned *United States of America v. LifeScan, Inc.*, No. CR _____(N.D. Cal., Dec. __, 2000).

E. Disclosure Program.

To the extent not already accomplished or within 90 days after the effective date of this CCA, LifeScan shall establish its own Disclosure Program, that must include a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with LifeScan's policies, conduct, practices, or procedures with respect to this CCA, believed by the individual to be a potential violation of criminal, civil or administrative law or the Program Requirements (a "Disclosure"). LifeScan shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communications. Upon receipt of a Disclosure, the Compliance Officer (or qualified designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or qualified designee) shall make a preliminary, good faith inquiry into the allegations set forth in every Disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any Disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, LifeScan shall conduct an internal review of the allegations set forth in such a Disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or his or her qualified designee) shall maintain a Disclosure log,

which shall include a record and summary of each Disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews.

The disclosure log shall be available to the OIG, upon request.

F. Ineligible Persons.

1. Definition. For purposes of this CCA, an "Ineligible Person" shall be any individual or entity who: (a) is currently excluded, debarred or otherwise ineligible to participate in the federal health care programs or in federal procurement or non-procurement programs; or (b) has been convicted of a criminal offense related to the provision of health care items or services, but has not yet been excluded, debarred or otherwise declared ineligible.

2. Screening Requirements. LifeScan shall not hire as a Relevant Covered Person any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, LifeScan shall screen all prospective employees and prospective contractors prior to engaging their services by: (a) requiring applicants to disclose whether they are Ineligible Persons; and (b) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.hhs.gov/oig) (these lists will hereinafter be referred to as the "Exclusion Lists").

3. Review and Removal Requirement. Within 90 days of the effective date of this CCA, LifeScan shall review its list of current Relevant Covered Persons against the Exclusion Lists. Thereafter, LifeScan shall review the Exclusion lists quarterly. In addition, LifeScan shall require Relevant Covered Persons to disclose immediately any debarment, exclusion or other event that makes the employee an Ineligible Person.

If LifeScan has notice that a Relevant Covered Person has become an Ineligible Person, LifeScan shall remove such person from responsibility for, or involvement with, LifeScan's business operations related to the federal health care programs and shall remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by federal health care programs or otherwise with federal funds at least until such time as the person is reinstated into participation in the federal health care programs.

4. Pending Charges and Proposed Exclusions. If LifeScan has notice that a Relevant Covered Person is charged with a criminal offense related to any federal health care program, or is proposed for exclusion during his or her employment or contract, LifeScan shall take all appropriate actions to ensure that the responsibilities of that Relevant Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient or

resident, or the accuracy of any claims submitted to any federal health care program.

G. Reporting of Material Deficiencies

1. *Definition of Material Deficiency.* For purposes of this CCA, a "Material Deficiency" means anything that involves the introduction or delivery into interstate commerce of what a reasonable person would consider to be a materially adulterated or misbranded medical device within the meaning of 21 U.S.C. § 352(a) for which a federal health care program was subsequently caused to pay. A Material Deficiency may be the result of an isolated event or a series of occurrences.

2. *Reporting of Material Deficiencies.* If LifeScan determines through any means that there is a Material Deficiency, LifeScan shall notify the OIG, in writing, within 30 days of making the determination that the Material Deficiency exists. The report to the OIG shall include the following information:

a. a complete description of the Material Deficiency, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

b. a description of LifeScan's actions taken to correct the Material Deficiency or the rationale for any decision not to take corrective action; and

c. any further steps LifeScan plans to take to address the Material Deficiency and prevent it from recurring.

H. Reporting

On an annual basis, LifeScan will certify that all events reportable to FDA pursuant to statute, regulation, or by agreement, have been reported.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the effective date of this CCA, LifeScan changes locations or purchases or establishes new business units related to items or services that may be reimbursed by federal health care programs, LifeScan shall notify the OIG of this fact as soon as possible, but no later than within 30 days of the date of change of location, purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Medicare provider number(s) (if any), and the corresponding contractor's name and address that has issued each Medicare provider number. All Covered Persons at such locations shall be subject to the applicable requirements in this CCA (e.g., completing certifications and

undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the effective date of this CCA, LifeScan shall submit a written report to the OIG summarizing the status of its implementation of the requirements of this CCA. This Implementation Report shall include:

1. the name, address, phone number, position description, and summary of other non-compliance job responsibilities of the Compliance Officer required by section III.A;

2. the names and positions of the members of the Project Team required by section III.A;

3. a copy of LifeScan's Code of Conduct required by section III.B.1;

4. a copy of all compliance-related Policies and Procedures required by section III.B.2 and a summary of all other Policies and Procedures required by section III.B.2;

5. a certification by the Compliance Officer that LifeScan has, to the best of his or her knowledge, complied with the requirements of Sections III.B. and III.C. relating to Policies and Procedures and Code of Conduct training; (The documentation supporting this certification shall be available to the OIG, upon request.)

6. a description of the Disclosure Program required by section III.E;

7. a summary of personnel actions (other than hiring) taken pursuant to section III.F.;

8. a list of all of LifeScan's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, and the corresponding phone numbers and fax numbers;

9. to the extent not already furnished to the OIG, or if modified, a description of LifeScan's corporate structure, including identification of any parent and sister companies, subsidiaries and their respective lines of business; and

10. the certification required by section V.C.

B. Annual Reports. LifeScan shall submit to the OIG Annual Reports with respect to the status of, and findings regarding, LifeScan's compliance activities for each of the three one-year periods beginning on the effective date of the CCA. (The one-year period covered by each Annual Report shall be referred to as the "Reporting Period").

Each Annual Report shall include:

1. any change in the identity, position description, or other non-compliance job responsibilities of the Compliance Officer and any change in the membership of the Project Team described in section III.A;

2. a certification by the Compliance Officer that LifeScan has, to the best of his or her knowledge, complied with the requirements of Section III.B.1 and III.C. relating to Code of Conduct training; (The documentation supporting this certification shall be available to the OIG, upon request.)

3. a summary of any significant changes or amendments to the Policies and Procedures required by section III.B and the reasons for such changes (e.g., change in contractor policy) and copies of any compliance-related Policies and Procedures;

4. a summary of the Disclosures in the Disclosure log required by section III.E that relate to federal health care programs;

5. a description of all changes to the most recently provided list (as updated) of LifeScan's locations (including locations and mailing addresses) as required by section V.A.7, the corresponding name under which each location is doing business, and the corresponding phone numbers and fax numbers; and

6. the certification required by section V.C.

The first Annual Report shall be received by the OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by the OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that: (1) except as otherwise described in the applicable report, LifeScan is in compliance with all of the requirements of this CCA, to the best of his or her knowledge; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information is accurate and truthful.

D. Designation of Information. LifeScan shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. LifeScan shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the effective date of this CCA, all notifications and reports required under this CCA shall be submitted to the following entities:

OIG:

Civil Recoveries Branch - Compliance Unit
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201
Phone 202.619.2078
Fax 202.205.0604

LifeScan:

Mr. Eric Milledge
Company Group Chairman
LifeScan, Inc.
1000 Gibraltar Drive
Milpitas, CA 95035
Phone 408.956.4900
Fax 408.942.5906

Unless otherwise specified, all notifications and reports required by this CCA may be made by certified mail, overnight mail, hand delivery or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

VII. OIG Inspection, Audit And Review Rights

In addition to any other rights the OIG may have by statute, regulation, or contract, the OIG or its duly authorized representative(s) may examine or request copies of LifeScan's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of LifeScan's locations for the purpose of verifying and evaluating LifeScan's compliance with the terms of this CCA. The documentation described above shall be made available by LifeScan to the OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, the OIG or its duly authorized representative(s) may interview any of LifeScan's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and the OIG. LifeScan agrees to assist the OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon the OIG's request. LifeScan's employees may elect to be interviewed with or without a representative of LifeScan present.

VIII. Document And Record Retention

LifeScan shall maintain for inspection all documents and records relating to compliance with this CCA, for one year longer than the term of the CCA (or longer if otherwise required by law).

IX. Disclosures

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify LifeScan prior to any release by the OIG of information submitted by LifeScan pursuant to its obligations under this CCA and identified upon submission by LifeScan as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, LifeScan shall have the rights set forth at 45 C.F.R. § 5.65(d). LifeScan shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA.

X. Breach And Default Provisions

LifeScan is expected to fully and timely comply with all of its CCA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, LifeScan and the OIG hereby agree that failure to comply with certain obligations set forth in this CCA may lead to the imposition of the following monetary penalties

(hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day that LifeScan fails to have in place any of the obligations described in section III:

a. a Compliance Officer;

b. a Project Team;

c. a written Code of Conduct;

d. written Policies and Procedures;

e. a requirement that Covered Persons be trained; and

f. a Disclosure Program.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day that LifeScan fails to meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to the OIG.

3. A Stipulated Penalty of $2,500 for each day that LifeScan fails to grant access to the information or documentation as required in section VII of this CCA. (This Stipulated Penalty shall begin to accrue on the date LifeScan fails to grant access.)

4. A Stipulated Penalty of $2,500 for each day LifeScan fails to comply fully and adequately with any obligation of this CCA. In its notice to LifeScan, the OIG shall state the specific grounds for its determination that LifeScan has failed to comply fully and adequately with the CCA obligation(s) at issue and steps LifeScan must take to comply with the CCA. (This Stipulated Penalty shall begin to accrue 10 days after the date that the OIG provides notice to LifeScan of the failure to comply.) A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under paragraphs 1-3 of this section.

B. Timely Written Requests for Extensions. LifeScan may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CCA. Notwithstanding any other provision in this section, if the OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after LifeScan fails to meet the revised deadline set by the OIG. Notwithstanding any other provision in this section, if the OIG denies such a timely written

request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after LifeScan receives the OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by the OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that LifeScan has failed to comply with any of the obligations described in section X.A. and after determining that Stipulated Penalties are appropriate, the OIG shall notify LifeScan of: (a) LifeScan's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days of the receipt of the Demand Letter, LifeScan shall either: (a) cure the breach and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section X.E. In the event LifeScan elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until LifeScan cures the alleged breach in dispute. Subject to the provisions of Section X.E., failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CCA and shall be grounds for monetary penalties for material breach of the CCA under section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to the OIG at the address set forth in section VI.

4. *Independence from Material Breach Determination.* Except as set forth in section X.D.1.c., these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for the OIG's decision that LifeScan has materially breached this CCA, which decision shall be governed by the provisions in section X.D., below.

D. Monetary Penalty for Material Breach of CCA

1. *Definition of Material Breach.* A material breach of this CCA means:

a. a failure by LifeScan to report a material deficiency and take corrective action, as required by section III.G.;

b. a repeated or flagrant violation of the obligations under this CCA, including, but not limited to, the obligations addressed in section X.A; or

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with section X.C.

2. *Notice of Material Breach.* The parties agree that an material breach of this CCA by LifeScan constitutes grounds for the OIG to impose an enhanced stipulated penalty that is separate and apart from the stipulated penalties described in section X.A. This monetary penalty (hereinafter referred to as the "Material Breach Penalty") shall be $25,000 per day, up to an aggregate maximum of $5,000,000. Upon a determination by the OIG that LifeScan has materially breached this CCA and that a Material Breach Penalty should be imposed, the OIG shall notify LifeScan by certified mail of: (i) the OIG's determination that LifeScan has materially breached this CCA; and (ii) the OIG's intent to exercise its contractual right to impose the Material Breach Penalty (this notification is hereinafter referred to as the "Notice of Material Breach Letter"). In its Notice of Material Breach Letter, the OIG shall state the specific grounds for its determination that LifeScan has materially breached this CCA.

3. *Opportunity for Cure.* LifeScan shall have 30 days from the date of receipt of the Notice of Material Breach Letter to demonstrate to the OIG's satisfaction that: (a) LifeScan is in full compliance with this CCA; (b) the alleged material breach has been cured; or (c) the alleged material breach cannot be cured within the 30 day period, but that (i) LifeScan has begun to take action to cure the material breach; (ii) LifeScan is pursuing such action with due diligence; and (iii) LifeScan has provided to the OIG a reasonable timetable for curing the material breach.

4. *Penalty Letter.* If, at the conclusion of the 30 day period, LifeScan fails to satisfy the requirements of Section X.D.3., the OIG may impose the Material Breach Penalty on LifeScan and the penalty will begin to accrue on that day. The OIG will notify LifeScan in writing of its determination to impose the Material Breach Penalty (this letter shall be referred to hereinafter as the "Material Breach Penalty Letter"). Within fifteen (15) calendar days after receipt of the Material Breach Penalty Letter, LifeScan shall either: (i) cure the material breach and pay the applicable Material Breach Penalty; or (ii) request a hearing before an ALJ to dispute the OIG's determination of material breach, pursuant to the agreed upon provisions set forth above in section X.E. In the event LifeScan elects to request an ALJ hearing, and subject to a decision by the ALJ in favor of the OIG, the potential Material Breach Penalties shall continue to accrue until LifeScan cures, to the OIG's satisfaction, the alleged material breach in dispute.

E. Dispute Resolution

1. *Review Rights.* Upon the OIG's delivery to LifeScan of its Demand Letter or of its Notice of Material Breach Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CCA, LifeScan shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or Material Breach Penalty sought pursuant to this CCA.

Specifically, the OIG's determination to demand payment of Stipulated Penalties or a Material Breach Penalty shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days of the receipt of the Demand Letter and the request for a hearing involving Material Breach Penalties shall be made within 25 days of receipt of the Notice of Material Breach Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CCA shall be: (a) whether LifeScan was in full and timely compliance with the obligations of this CCA for which the OIG demands payment; and (b) the period of noncompliance. LifeScan shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ agrees with the OIG with regard to a finding of a breach of this CCA and orders LifeScan to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless LifeScan requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of the OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Material Breach Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding regarding imposition of the Material Breach Penalty shall be:

a. whether LifeScan was in material breach of this CCA;

b. whether LifeScan had cured the material breach by the date of the Material Breach Penalty Letter; and

c. whether the alleged material breach could not have been cured within the 30 day period, but that:

(i) LifeScan had begun to take action to cure the material breach within that period;

(ii) LifeScan has pursued and is pursuing such action with due diligence; and

(iii) LifeScan provided to the OIG within that period a reasonable timetable for curing the material breach and LifeScan has followed the timetable.

If LifeScan invokes the Dispute Resolution Procedures in this section, the Material Breach Penalty shall be imposed only after an ALJ decision (or, if applicable, a DAB decision) which is favorable to the OIG. If it is determined that a Material Breach Penalty shall be imposed, the applicable Material Breach Penalty will be based on the number of days between the date of the Material Breach Penalty Letter and the date of the ALJ decision (or, if applicable, DAB decision) favorable to the OIG. If the ALJ sustains the OIG's decision and determines that the imposition of such penalty is authorized, payment of the Material Breach Penalty will be required within twenty (20) days after the ALJ issues such a decision or within twenty (20) days after a DAB decision upholding the ALJ decision if LifeScan seeks review by the DAB.

4. *No Limitation of Remedies.* Nothing in this Section X.E. shall be construed to limit LifeScan's right to seek review of an administrative decision under this CCA regarding Stipulated Penalties or Material Breach Penalties in federal court, provided however, that the OIG does not concede that a federal court would have jurisdiction over such a matter.

XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which this CCA is entered, and into which this CCA is incorporated, LifeScan and the OIG agree as follows:

A. This CCA shall be binding on the successors, assigns, and transferees of LifeScan;

B. This CCA shall become final and binding on the date the final signature is obtained on the CCA;

C. Any modifications to this CCA shall be made with the prior written consent of the parties to this CCA;

D. The OIG may agree to a suspension of LifeScan's obligations under the CCA in the event LifeScan discontinues sales to suppliers and/or providers participating in federal health care programs. If LifeScan discontinues such sales and is relieved from its CCA obligations by the OIG, LifeScan agrees to notify the OIG 30 days in advance of LifeScan's intent to resume such sales or to apply as a participating provider or supplier with the federal health care programs. Upon receipt of such notification, the OIG will evaluate whether the CCA should be reactivated or modified.

E. The undersigned LifeScan signatories represent and warrant that they are authorized to execute this CCA. The undersigned the OIG signatory represents that he is signing this CCA in his official capacity and that he is authorized to execute this CCA.

ON BEHALF OF LIFESCAN, INC.

	12/13/00
LifeScan, Inc.	DATE
Counsel for LifeScan, Inc.	DATE

ON BEHALF OF LIFESCAN, INC.

LifeScan, Inc.	DATE
Eugene Tillman /jm Counsel for LifeScan, Inc.	12/12/00 DATE

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

LEWIS MORRIS
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

12/13/00
DATE